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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/584,936	05/31/2000	Michael G. Kahn M.D. Ph.D	FSTK 1000-0	5001

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EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/584,936	KAHN M.D. PH.D ET AL.	
	Examiner	Art Unit	
	LENA NAJARIAN	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5, 7- 30, 36, 45-109, 118, 137, 139 and 140* is/are pending in the application.

4a) Of the above claim(s) *7,12-30,36,45-109,118 and 137* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8-11,139 and 140* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the Request for Continued Examination (RCE) filed 3/24/08. No claims have been amended. Applicant has submitted two second declarations. Claims 1-5, 8-11, and 139-140 are rejected.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/24/08 has been entered.

Claim Objections

3. Claims 1 and 4 are objected to because of the following informalities: the meaning of acronym “CRF” is unclear. The Examiner suggests Applicant change “CRF” to “Case Report Form." Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-5, 8-11 and 139-140 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 recites the limitation "at least one element of the group consisting of a post-enrollment instruction to have a specified test performed on the patient, and a post-enrollment instruction to have a specified CRF completed for the patient" in lines 6-8. Claim 4 recites "wherein said first plurality of workflow tasks includes the post-enrollment instruction to have a specified CRF completed for the patient" and claims 5 and 140 subsequently require "wherein said post-enrollment workflow tasks further include the post-enrollment instruction to have a specified test performed on the patient." Therefore, it is unclear whether a specified test and a specified CRF are both required or if they are in the alternative only.

7. Claims 2-3, 8-11, and 139 incorporate the deficiencies of claims 1, 4, 5, and 140, through dependency, and are also rejected.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 2, 4, 10, 11, and 139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al. (5,991,731) in view of Gillings et al. (5,666,490).

(A) Referring to claim 1, Colon discloses at least one computer readable medium collectively carrying a machine readable database identifying (abstract of Colon):

first patient eligibility criteria for a first clinical trial protocol (col. 6, lines 39-42 of Colon); and

a first plurality of workflow tasks for said first clinical trial protocol, said first plurality of workflow tasks including post-enrollment workflow tasks to be performed for a particular patient (col. 6, line 39 – col. 7, line 10 of Colon).

Colon does not disclose wherein the post-enrollment workflow tasks include at least one element of the group consisting of a post-enrollment instruction to have a specified test performed on the patient, and a post-enrollment instruction to have a specified CRF completed for the patient.

Gillings discloses wherein the post-enrollment workflow tasks include a post-enrollment instruction to have a specified CRF completed for the patient (col. 5, lines 12-30 of Gillings).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Gillings within Colon. The motivation for doing so would have been to better manage clinical trial data (col. 1, lines 65-67 of Gillings).

Insofar as the claim recites "at least one element of the group consisting of," it is immaterial whether or not the other elements are also disclosed.

(B) Referring to claim 2, Colon discloses wherein said database further identifies preliminary patient eligibility criteria applicable to said first clinical trial protocol (col. 2, lines 5-8 of Colon).

(C) Referring to claim 4, Colon does not disclose wherein said first plurality of workflow tasks includes the post-enrollment instruction to have a specified CRF completed for the patient.

Gillings discloses wherein said first plurality of workflow tasks includes the post-enrollment instruction to have a specified CRF completed for the patient (col. 5, lines 12-30 of Gillings).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Gillings within Colon. The motivation for doing so would have been better manage clinical trial data (col. 1, lines 65-67 of Gillings).

(D) Referring to claim 10, Colon discloses wherein said first plurality of workflow tasks include an instruction to enroll a patient into a clinical trial (col. 5, lines 25-35 of Colon).

(E) Referring to claim 11, Colon discloses wherein said first plurality of workflow tasks include an instruction to enroll a patient into a clinical trial (col. 5, lines 25-35 of Colon).

(F) Referring to claim 139, Colon discloses wherein said post-enrollment workflow tasks include patient management tasks (col. 6, lines 1-14 of Colon).

10. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al. (5,991,731) in view of Gillings et al. (5,666,490), and further in view of Cimino ("Distributed cognition and knowledge-based controlled medical terminologies").

(A) Referring to claim 3, Colon and Gillings do not disclose wherein said database identifies a term by reference to a controlled medical terminology database.

Cimino teaches that controlled medical terminologies (CMTs) are at the heart of most medical systems (pages 154 & 162 of Cimino).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Cimino within Colon and Gillings. The motivation for doing so would have been to enable data sharing and coordination of multiple applications (page 161 of Cimino).

11. Claims 5 and 140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al. (5,991,731) in view of Gillings et al. (5,666,490), and further in view of Coli et al. (6,018,713).

(A) Referring to claims 5 and 140, Colon and Gillings do not disclose wherein said post-enrollment workflow tasks further include the post-enrollment instruction to have a specified test performed on the patient.

Coli discloses wherein said post-enrollment workflow tasks further include the post-enrollment instruction to have a specified test performed on the patient (col. 4, line 62 - col. 5, line 31 of Coli).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Coli within Colon and Gillings. The motivation for doing so would have been to enhance communication by providing the ability to order necessary medical tests (col. 4, lines 52-61 of Coli).

12. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al. (5,991,731) in view of Gillings et al. (5,666,490), and further in view of McAlindon et al. (US 7,251,609 B1).

(A) Referring to claims 8 and 9, Colon and Gillings do not disclose wherein said first plurality of workflow tasks includes an instruction to obtain specified patient medical information before an instruction to obtain informed consent and wherein said first plurality of workflow tasks includes a pre-enrollment instruction to obtain specified patient medical information after said instruction to obtain informed consent.

McAlindon discloses wherein said first plurality of workflow tasks includes an instruction to obtain specified patient medical information before an instruction to obtain informed consent and wherein said first plurality of workflow tasks includes a pre-enrollment instruction to obtain specified patient medical information

after said instruction to obtain informed consent (col. 4, lines 37-45 and col. 5, lines 5-25 of McAlindon).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of McAlindon within Colon and Gillings. The motivation for doing so would have been to gather the necessary information and follow the procedures in order to allow the candidate to participate in the clinical trial (col. 5, lines 5-25 of McAlindon).

Affidavits

13. The declarations filed on 3/24/08 under 37 CFR 1.131 are sufficient to overcome the Briegs (US 7,054,823 B1) reference.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches a method and apparatus for clinical trials (US 6,687,190 B2); an integrated disease information system (6,108,635); a computerized system for conducting medical studies (US 6,839,678 B1); a database creating method using image information (5,930,799); and a drug document production system (5,963,967).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LENA NAJARIAN whose telephone number is

(571) 272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. N./
Examiner, Art Unit 3626
ln
5/29/08

/Robert Morgan/
Primary Examiner, Art Unit 3626